PMA Monthly approvals from 4/1/2020 to 4/30/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190026	04/15/2020	PMAO - PMA Origi	THERASCREEN BRAF V600E RGQ PCR KIT	QIAGEN GMBH	Approval for the therascreen BRAF V600E RGQ PCR Kit. The therascreen BRAF V600E RGQ PCR Kit is a real-time PCR test for the qualitative detection of V600E mutations in the BRAF gene using genomic DNA extracted from formalin-fixed paraffin-embedded (FFPE) human colorectal cancer (CRC) tumor tissue. The therascreen BRAF V600E RGQ PCR Kit is an in vitro diagnostic device intended to be used as an aid in selecting patients with metastatic colorectal cancer (mCRC) whose tumors carry the BRAF V600E mutation for treatment with BRAFTOVI (encorafenib) in combination with cetuximab. The therascreen BRAF V600E RGQ PCR Kit is for use on the Rotor-Gene Q MDx (US) instrument. The therascreen BRAF V600E RGQ PCR Kit is intended for in vitro diagnostic use.
P190027	04/10/2020	PMAO - PMA Origi	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	INTACT VASCULAR, INC.	Approval for use in mid/distal popliteal, tibial and peroneal arteries, ranging in diameter from 1.5 mm to 4.5 mm, for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).
P190028	04/03/2020	PMAO - PMA Origi	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the cobas HPV for use on the cobas 6800/8800 Systems. cobas HPV for use on the cobas 6800/8800 Systems (cobas HPV) is a qualitative in vitro test for the detection of Human Papillomavirus in clinician-collected cervical specimens using an endocervical brush/spatula or broom and placed in the ThinPrep Pap Test PreservCyt Solution. This test detects the high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. cobas HPV is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors.
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Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S247	04/01/2020	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P830055/S244	04/30/2020	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to introduce an inspection at the assembly process step to ensure the correct screw is packaged with the MBT Step Wedge components.

Data as of 05/04/2020 03:23 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S173	04/23/2020	N - Normal 180 Day	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P860057/S196	04/10/2020	O - Normal 180 Day	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.
P890003/S416	04/23/2020	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P910007/S052	04/10/2020	R - Real-Time Proc	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Approval to implement of new lot of ARCHITECT Total PSA Secondary Calibrators A through F.
P910018/S027	04/21/2020	N - Normal 180 Day	LIPOSORBER LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Approval for modification to the indications for use statement to include a new Group D - "Functional Hypercholesterolemic Heterozygotes with LDL-C >= 100 mg/dl and lipoprotein (a) [Lp(a)] >= 60 mg/dL, and either documented coronary artery disease or documented peripheral artery disease."
P910077/S176	04/01/2020	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P920015/S234	04/23/2020	N - Normal 180 Day	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P930039/S202	04/23/2020	N - Normal 180 Day	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P960040/S446	04/01/2020	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P960058/S145	04/03/2020	N - Normal 180 Day	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval of AIM Sound Tubes, a non-sterile ear insert to be used with the AIM System, and related labeling, which are part of the HiResolution Bionic Ear System.
P970051/S188	04/02/2020	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for Remote Check, a clinician-enabled option for the Nucleus Smart App, that allows clinicians to monitor the performance of the associated implant system remotely.
P980016/S713	04/23/2020	N - Normal 180 Day	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S514	04/01/2020	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P010014/S097	04/27/2020	Y - 135 Review Tra	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval to revise the Ultra-High Molecular Weight Polyethylene (UHMWPE) Direct Compression Molding (DCM) manufacturing process for the Oxford Partial Knee System meniscal bearings.
P010030/S133	04/20/2020	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for version V07.9M3 of the software for the WCD 4000 monitor.
P010031/S674	04/23/2020	N - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P030005/S193	04/01/2020	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P030036/S111	04/23/2020	N - Normal 180 Day	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P040014/S039	04/24/2020	R - Real-Time Proc	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for a new pouch materials, pouch seal strength, and pouch sealer changes.
P040034/S030	04/08/2020	O - Normal 180 Day	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for a manufacturing site located at Steris Isomedix Operations, 2 Nucifora Boulevard, Chester, New York 10918, to provide electron beam sterilization of the DuraSeal Exact System and DuraSeal Dural Sealant System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040042/S045	04/24/2020	R - Real-Time Proc	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for a new pouch materials, pouch seal strength, and pouch sealer changes.
P050010/S020	04/10/2020	P - Panel Track	PRODISC -L TOTAL DISC REPLACEMENT DEVICE	CENTINEL SPINE, LLC	Approval for the prodisc® L Total Disc Replacement. The prodisc® L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one or two adjacent vertebral level(s) from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level(s). Patients receiving the prodisc® L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the prodisc® L Total Disc Replacement.
P050038/S035	04/29/2020	R - Real-Time Proc	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Approval for a change to the instructions for use on the cardiotomy filter size range to include a 20-40 micron size range for autologous blood salvage systems compatible with the device.
P060019/S047	04/24/2020	R - Real-Time Proc	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Approval for a new pouch materials, pouch seal strength, and pouch sealer changes.
P080004/S028	04/23/2020	O - Normal 180 Day	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for packaging changes for the iSert® Preloaded System Platform Models 230 and 231. The device, as modified, will be marketed under the trade name IPure Preloaded IOL System Model B3PC and B3PY.
P080004/S030	04/17/2020	O - Normal 180 Day	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for packaging changes for the iSert® Preloaded System Platform Models 250 and 251. This device, as modified, will be marketed under the tradename IPure Preloaded System Platform Models B1PC and B1PY and is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.
P080006/S137	04/23/2020	N - Normal 180 Day	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P080013/S018	04/08/2020	O - Normal 180 Day	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for a manufacturing site located at Steris Isomedix Operations, 2 Nucifora Boulevard, Chester, New York 10918, to provide electron beam sterilization of the DuraSeal Exact System and DuraSeal Dural Sealant System.
P090013/S301	04/23/2020	N - Normal 180 Day	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Approval for Cobalt XT, Cobalt, and Crome MRI SureScan Implantable Cardioverter Defibrillator (ICD) and ICD with Cardiac Resynchronization Systems.
P100042/S027	04/27/2020	N - Normal 180 Day	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval for the use of ThinPrep 5000 post-processed samples on the Aptima HPV Assay.
P100044/S045	04/24/2020	S - Special CBE	PROPEL	INTERSECT ENT	Approval for modifications to the Instructions for Use (IFU) to enhance the safe use of the Propel Family of Implants (Propel, Propel Mini and Propel Contour).
P100047/S144	04/24/2020	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a new test system, the HVAD HQ EOL Test System, as the product acceptance test for the HVAD Pump.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110008/S011	04/07/2020	O - Normal 180 Day	COFLEX® INTERLAMINAR TECHNOLOGY	RTI SURGICAL, INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110016/S067	04/24/2020	R - Real-Time Proc	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for new pouch materials, pouch seal strength, and pouch sealer changes.
P110019/S109	04/06/2020	R - Real-Time Proc	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval to extend the shelf-life for the XIENCE Sierra Everolimus-Eluting Coronary Stent System from 12 to 18 months.
P110042/S133	04/01/2020	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P120007/S025	04/27/2020	N - Normal 180 Day	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for the use of ThinPrep 5000 post-processed samples on the Aptima HPV 16 18/45 Genotype assay.
P130008/S039	04/14/2020	P - Panel Track	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the Inspire Upper Airway Stimulation (UAS) the device is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as: 1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or 2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it). Inspire UAS is also indicated for use in patients between the ages of 18 and 21with moderate to severe OSA (15<=AHI<=65) who: 1) Do not have complete concentric collapse at the soft palate level; 2) Are contraindicated for or not effectively treated by adenotonsillectomy; 3) Have been confirmed to fail, or cannot tolerate PAP therapy despite attempts to improve compliance; and 4) Have followed standard of care in considering all other alternative/adjunct therapies.
P130009/S105	04/10/2020	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.
P130016/S039	04/02/2020	N - Normal 180 Day	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for Remote Check, a clinician-enabled option for the Nucleus Smart App, that allows clinicians to monitor the performance of the associated implant system remotely.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130022/S028	04/25/2020	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for use of alternate proposed Integer battery (M3580) on Senza Implantable Pulse Generator, model IPG2000 (Senza II) of Nevro's Senza Spinal Cord Stimulator (SCS) System and associated firmware updates.
P130022/S031	04/02/2020	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for additional lead sizes and configurations designated as Surpass-C Surgical Leads.
P140003/S068	04/01/2020	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a labeling change related to the use of the Automated Impella Controller (AIC) during air transport.
P140003/S070	04/17/2020	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for software changes (v8.3).
P140018/S019	04/10/2020	S - Special CBE	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for a change to the Instructions for Use for the VenaSeal Closure System that further defines the exiting steps.
P140028/S053	04/16/2020	R - Real-Time Proc	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a change to the material of construction for a delivery system component.
P140031/S102	04/10/2020	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.
P150005/S049	04/17/2020	N - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the DirectSense RF feature in the Rhythmia HDx Mapping System Software Version 4.0 to be used in conjunction with the IntellaNav MiFi Open-Irrigated Ablation Catheter during cardiac ablation.
P150012/S088	04/01/2020	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System, Release 6.1.5 and associated changes in Server and Communicator software updates.
P150024/S016	04/24/2020	O - Normal 180 Day	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval including the ODE Lead PMA Post-Approval Study - Extended Follow-up of the Premarket Cohort (PATHWAY Clinical Trial) has been fulfilled.
P150031/S026	04/10/2020	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updates to the Vercise Neural Navigator Clinician Programmer Software.
P150036/S048	04/10/2020	O - Normal 180 Day	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.
P150037/S014	04/09/2020	O - Normal 180 Day	CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Approval of the protocol for the post-approval study (PAS) referenced above. The PAS protocol has been submitted to comply with the letter dated October 10, 2019 requesting that you continue the assessment of subjects implanted with the device for a minimum of 10 years to assess the long-term safety profile of the CyPass® System.
P150038/S012	04/14/2020	N - Normal 180 Day	EXABLATE	INSIGHTEC	Approval for changes to the Exablate Neuro to introduce software version 7.33, expand the use of the device with an additional Siemens 1.5 Tesla (T) Aera magnetic resonance imaging (MRI) scanner, and addition of a custom 1.5 T receive-only imaging coil for the Exablate 4000 Type 1.1 System and a custom 3.0 T receive-only imaging coil for the Exablate 4000 Type 1.0 System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150046/S004	04/30/2020	N - Normal 180 Day	NEVISENSE	SCIBASE AB	Approval for software changes to remove the reference measurement step from the device operation, introducing an in-device qualification module and lesion feedback mechanism to detect potential user errors.
P150048/S043	04/10/2020	O - Normal 180 Day	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.
P160008/S009	04/30/2020	R - Real-Time Proc	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Approval for labeling changes for the SAM350P, SAM360P and SAM 450P public access defibrillators and Pad-Pak accessories.
P160032/S004	04/22/2020	R - Real-Time Proc	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for software updates to the self-test features for the DDU-2000 series AEDs.
P160042/S011	04/21/2020	R - Real-Time Proc	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval of change of shelf-life from 12 months to 18 months for Revanesse Versa+.
P160043/S031	04/09/2020	R - Real-Time Proc	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for introducing changes to the material of the desiccant (molecular sieve material) added to the product packaging post sterilization of the Resolute Onyx product.
P170003/S016	04/21/2020	R - Real-Time Proc	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for a new colorant in the base catheter and an increase in marker band length for the Lutonix 018 Drug Coated Balloon PTA Catheter.
P170011/S021	04/01/2020	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a labeling change related to the use of the Automated Impella Controller (AIC) during air transport.
P170019/S013	04/17/2020	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order for extending the label claim to include an indication for PEMAZYRE (pemigatinib)in cholangiocarcinoma patients with FGFR2 fusions and select rearrangements.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170043/S006	04/30/2020	O - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170043/S007	04/30/2020	O - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180011/S024	04/01/2020	O - Normal 180 Day	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the revised protocols for the post-approval studies (PAS) protocol, including terminating enrollment in the REGAL study and extending follow-up to five years for the EMINENT study.
P180011/S025	04/16/2020	R - Real-Time Proc	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change to the material of construction for a delivery system component.
P180014/S003	04/24/2020	R - Real-Time Proc	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval for a software upgrade for the XPS System (software version V.5.2.0).
P180014/S004	04/26/2020	R - Real-Time Proc	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval for a change in the ventilator included in the XPS System to use the Hamilton C3 Ventilator.
P180038/S001	04/08/2020	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for System software update from software version 4.2.1.1 to software version 4.2.2.2 on the LIAISON® XL analyzer.
P180046/S001	04/15/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for software modifications to the Axonics Clinician Programmer (Model 2501) and associated labeling changes to enable use with the existing External Trial Stimulator and the existing Implanted Neurostimulator.
P180046/S002	04/15/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the Charging Device (Model 1401), including a new rechargeable lithium-ion battery and associated software and specification changes, a new speaker, and the addition of foam spacers between the battery and coil.
P180046/S004	04/19/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the IPG Charging interval time.
P180047/S002	04/08/2020	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for System software update from software version 4.2.1.1 to software version 4.2.2.2 on the LIAISON® XL analyzer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190006/S004	04/13/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the IPG Charging interval time.
P190008/S001	04/10/2020	O - Normal 180 Day	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval of the revised protocol for the New Enrollment IN.PACT AV Access PAS.
P190011/S001	04/08/2020	R - Real-Time Proc	LIAISON XL MUREX HCV AB; LIAISON XL MUREX CONTROL HCV AB	DIASORIN INC.	Approval for System software update from software version 4.2.1.1 to software version 4.2.2.2 on the LIAISON® XL analyzer.
P190014/S001	04/29/2020	N - Normal 180 Day	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval for extending the label claim to include an additional indication for Zejula® (niraparib) maintenance therapy. The device, as modified, will be marketed under the trade name Myriad myChoice® CDx and is indicated for: Myriad myChoice® CDx is a next generation sequencing-based in vitro diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status, who are eligible, because of a positive test result for deleterious or suspected deleterious mutations in BRCA1 or BRCA2 genes, or may become eligible, because of a positive test result for deleterious or suspected deleterious mutations in BRCA1 or BRCA2 genes or a positive Genomic Instability Score, for treatment with the approved targeted therapy Zejula® (niraparib). Detection of deleterious or suspected deleterious BRCA1 and BRCA2 and/or positive Genomic Instability Score in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy. This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, Inc., a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108.

Total: 80

30-Day Notice

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N12159/S070	04/13/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Qualification of a replacement SURGICEL SNoW Expander equipment at Janssen Pharmaceuticals, Inc.
N16895/S103	04/13/2020	X - 30-Day Notice	SOFLENS CONTACT LENSES (POLYMACON)	BAUSCH & LOMB, INC.	Change from the use of animal to vegetable-based additives in the production of resin used to make casting molds for production of Soflens® (polymacon) and Soflens® Toric (alphafilcon A) contact lenses at the Rochester, NY and Waterford, Ireland manufacturing sites.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17600/S033	04/09/2020	X - 30-Day Notice	AVITENE (MICROFIBRILLAR COLLAGEN HOMOSTAT)	DAVOL, INC., SUB. C.R. BARD, INC.	Change in the test method for the in-process measurement of hydroxyproline in Avitene bulk flour and finished product.
N970012/S176	04/09/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Changes to the molding process of the rear tip component
P800002/S026	04/09/2020	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT NON-WOVEN WEB	C.R. BARD, INC.	Change in the test method for the in-process measurement of hydroxyproline in Avitene bulk flour and finished product.
P830055/S243	04/22/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in Chemical Formulation and Cleaning Detergent for Final Cleaning Process for several Knee components.
P830055/S246	04/29/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Laser marking equipment added to the manufacturing process.
P830061/S180	04/06/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a web user interface to replace the current Windows-based graphical user interface to the Manufacturing Execution System.
P840001/S458	04/07/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Changes to the restock evaluation location and process for the SynchroMed II Infusion System.
P840001/S459	04/22/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Reduction in frequency of Destructive Analysis (DA) sampling performed on battery headers undergoing laser welding at Medtronic Energy and Component Center.
P840064/S071	04/02/2020	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Use of the Bulk Syringe Line (BSL) as an additional alternate syringe processing and filling line to fill PROVISC, DISCOVISC® and PROVISC® as part of DUOVISC®.
P850079/S087	04/20/2020	X - 30-Day Notice	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	Installation and qualification of an additional de-ionized (DI) water plant at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom. .
P860004/S353	04/02/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Clarify the USON Backflow test acceptance criteria for the test of the SynchroMed II implantable infusion pump to be more conservative.
P860004/S354	04/07/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Changes to the restock evaluation location and process for the SynchroMed II Infusion System.
P860004/S355	04/22/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Reduction in frequency of Destructive Analysis (DA) sampling performed on battery headers undergoing laser welding at Medtronic Energy and Component Center.
P870024/S053	04/20/2020	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Software update for generating lathe cutting files for Paragon CRT®100 (paflufocon D) and Paragon CRT Dual Axis® (paflufocon D) Rigid Gas Permeable contact lenses in clear and tints.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890047/S054	04/02/2020	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Use of the Bulk Syringe Line (BSL) as an additional alternate syringe processing and filling line to fill PROVISC, DISCOVISC® and PROVISC® as part of DUOVISC®.
P930014/S129	04/23/2020	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Modifications to enable the automation of the nozzle coating process at Alcon Laboratories in Ireland as part of the manufacturing process for the AcrySof® IQ Aspheric IOL with UltraSert® Preloaded Delivery System, Model AU00T0.
P930036/S014	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P950005/S074	04/16/2020	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.
P950020/S107	04/02/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Automation of a component manufacturing process.
P950021/S021	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P950037/S212	04/22/2020	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Implement an automated process for stamping lithium foil pieces for the anodes of the batteries used in IPGs and ICDs.
P960009/S371	04/07/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Changes to the restock evaluation location and process for the SynchroMed II Infusion System.
P960009/S372	04/22/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Reduction in frequency of Destructive Analysis (DA) sampling performed on battery headers undergoing laser welding at Medtronic Energy and Component Center.
P960016/S081	04/16/2020	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Addition of an alternative bacterial endotoxin testing method.
P960016/S082	04/13/2020	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Removal of redundant in-process pull tests performed during the sub-assembly manufacturing process.
P960022/S012	04/13/2020	X - 30-Day Notice	SOFLENS66(TM)	BAUSCH & LOMB, INC.	Change from the use of animal to vegetable-based additives in the production of resin used to make casting molds for production of Soflens® (polymacon) and Soflens® Toric (alphafilcon A) contact lenses at the Rochester, NY and Waterford, Ireland manufacturing sites.
P960040/S451	04/07/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add an automated visual inspection system to the battery manufacturing process.
P970054/S018	04/21/2020	X - 30-Day Notice	BIOTRIN PARVOVIRUS B19 IGG	DIASORIN	Replace a critical raw material (and its supplier) used in the shipment of manufactured kits.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970055/S020	04/21/2020	X - 30-Day Notice	BIOTRIN PARVOVIRUS IGM EIA (V619IMUS)	DIASORIN	Replace a critical raw material (and its supplier) used in the shipment of manufactured kits.
P980016/S732	04/02/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement a new inspection method for select manufacturing parts.
P980016/S733	04/06/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update gas content monitoring samples.
P980016/S734	04/06/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the Distribution Control Sorter Tool to make it compatible with other products.
P980016/S735	04/15/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modifications of the seam weld inspection and backfill hole weld rework processes.
P980016/S736	04/14/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the Soft Straight Line Finish rework process used at the final device manufacturing facility.
P980016/S737	04/22/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the assessment of device bioburden procedure.
P980016/S738	04/23/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement a modified prebake process at supplier.
P980023/S101	04/22/2020	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Implement an automated process for stamping lithium foil pieces for the anodes of the batteries used in IPGs and ICDs.

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P980035/S621	04/06/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Distribution Control Sorter Tool to make it compatible with other products.
P980035/S622	04/15/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications of the seam weld inspection and backfill hole weld rework processes.
P980035/S623	04/14/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Soft Straight Line Finish rework process used at the final device manufacturing facility.
P980035/S624	04/22/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the assessment of device bioburden procedure.
P980037/S080	04/13/2020	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Update to the sterilization cycle at the BSC Coventry, Rhode Island facility and the Steris Tullamore, Ireland contract sterilization facility.
P990004/S038	04/14/2020	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	New pallet configuration for the Gamma irradiation of SURGIFLO Hemostatic Matrix Intermediate.
P990025/S059	04/16/2020	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.
P990055/S021	04/03/2020	X - 30-Day Notice	BAYER IMMUNO 1 COMPLEXED PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P990071/S043	04/16/2020	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.
P000009/S085	04/22/2020	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Implement an automated process for stamping lithium foil pieces for the anodes of the batteries used in IPGs and ICDs.
P000039/S069	04/15/2020	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Reduce the inspection frequency of braided wire mandrels.
P000039/S070	04/16/2020	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Addition of an alternative bacterial endotoxin testing method.

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P010012/S519	04/07/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add an automated visual inspection system to the battery manufacturing process.
P010015/S431	04/06/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the Distribution Control Sorter Tool to make it compatible with other products.
P010015/S432	04/15/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modifications of the seam weld inspection and backfill hole weld rework processes.
P010015/S433	04/14/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the Soft Straight Line Finish rework process used at the final device manufacturing facility.
P010015/S434	04/22/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the assessment of device bioburden procedure.
P010029/S030	04/16/2020	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Change in manufacturing to shorten the time required for the concentration step during formulation by slightly increasing the pressure and reducing the concentration time in the UF (ultrafiltration) unit.
P010030/S134	04/18/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Change in the manufacturing location of the supplier for the Electrode Belt Therapy foam cover for the LifeVest 4000 and LifeVest 4000B.
P010030/S135	04/16/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Change the concentration of the disinfectant used for returned equipment to match EPA recommendations for coronavirus.
P010031/S693	04/02/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new inspection method for select manufacturing parts.
P010031/S694	04/06/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update gas content monitoring samples.

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P010031/S695	04/06/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Distribution Control Sorter Tool to make it compatible with other products.
P010031/S696	04/15/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications of the seam weld inspection and backfill hole weld rework processes.
P010031/S697	04/14/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Soft Straight Line Finish rework process used at the final device manufacturing facility.
P010031/S698	04/22/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the assessment of device bioburden procedure.
P010031/S699	04/23/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a modified prebake process at supplier.
P010068/S059	04/16/2020	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.
P020004/S174	04/10/2020	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	New ethylene oxide sterilization cycle at Sterigenics in Los Angeles, California.
P020024/S059	04/15/2020	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Reduce the inspection frequency of braided wire mandrels.

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P020024/S060	04/16/2020	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Addition of an alternative bacterial endotoxin testing method.
P030017/S334	04/17/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate sterilization facility for the Entrada Needle and Sheath.
P030017/S335	04/24/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an additional ethylene oxide (EO) sterilization chamber and associated sterilization process located at Boston Scientific Dorado Manufacturing site (BSC-DOR).
P030031/S104	04/16/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.
P030031/S105	04/30/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Alternative automated dimensional inspection process for ring spacing, tip length and shaft outer diameter for the ThermoCool SmartTouch family of catheters.
P030040/S017	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P030056/S016	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P040004/S017	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P040021/S043	04/25/2020	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	New supplier for polyester thread.
P040036/S072	04/16/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Introduce a new ballast spacer material and increased maximum load capacity to be used in the sterilization of Biosense Webster ablation catheters and cables.

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P040036/S073	04/30/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Alternative automated dimensional inspection process for ring spacing, tip length and shaft outer diameter for the ThermoCool SmartTouch family of catheters.
P040040/S039	04/15/2020	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Reduce the inspection frequency of braided wire mandrels.
P040040/S040	04/16/2020	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Addition of an alternative bacterial endotoxin testing method.
P040043/S114	04/10/2020	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	New ethylene oxide sterilization cycle at Sterigenics in Los Angeles, California.
P040047/S057	04/15/2020	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Removal of obsolete equipment.
P050006/S082	04/10/2020	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	New ethylene oxide sterilization cycle at Sterigenics in Los Angeles, California.
P050023/S146	04/22/2020	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Implement an automated process for stamping lithium foil pieces for the anodes of the batteries used in IPGs and ICDs.
P050037/S103	04/15/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Removal of obsolete equipment.
P050042/S043	04/29/2020	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Change in supplier's manufacturing site of a critical assay component.
P050052/S121	04/15/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Removal of obsolete equipment.
P060040/S077	04/09/2020	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Qualify an alternate sub-supplier for the polyester raw material used in the manufacture of the HeartMate II Apical Sewing Ring and Percutaneous Cable as well as the HeartMate 3 Percutaneous Cable.
P070004/S031	04/02/2020	X - 30-Day Notice	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Add one (1) new vacuum pump and four (4) new vacuum chambers.
P070006/S013	04/03/2020	X - 30-Day Notice	T SPOT-TB TEST	OXFORD IMMUNOTEC,LTD.	Addition of an alternative nonsterile raw material.
P070026/S071	04/22/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change to the coating process of the CERAMAX Ceramic Total Hip System at the DePuy Ireland manufacturing facility.
P080011/S104	04/01/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Validate Biofinity Line 20 at the Hamble, United Kingdom manufacturing facility to produce Biofinity Toric lenses.
P080011/S105	04/20/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Installation and qualification of an additional de-ionized (DI) water plant at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom. .

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090015/S011	04/24/2020	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Addition of a new supplier of reagent.
P090024/S008	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR HBEAG ASSAY AND QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P090029/S014	04/15/2020	X - 30-Day Notice	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Change in the manufacturing process for machining of the Upper and Lower system components; and (2) a change to the packaging process for packaging the as sterilized Prestige LP Cervical Disc implants.
P100021/S080	04/02/2020	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to the stent ring passivation process.
P100026/S080	04/06/2020	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Implement minor manufacturing changes to the die attach process and transfer mold process used for fabricating the RNS Neurostimulator (model RNS-320) stacked die ball grid array (SDBGA).
P100039/S009	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P100045/S042	04/14/2020	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Addition of a chemical fume hood to be used for the chemical wet processes.
P100047/S155	04/01/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change in location for the manufacture of a component of the HeartWare Ventricular Assist System (HVAS).
P100047/S157	04/08/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change to the glycerol source used for the HVAD pump functional wet test.
P110002/S024	04/16/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Modification of manufacturing process of the Mobi-C trials.
P110004/S035	04/09/2020	X - 30-Day Notice	PRESILLION PLUS COCR CORONARY STENT RX SYSTEM	MEDINOL LTD.	Expand the use of automation for the hydrophilic coating line of the delivery catheter.
P110009/S024	04/16/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Modification of manufacturing process of the Mobi-C trials.
P110010/S177	04/03/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Adding automation equipment for various steps of the primer and drug solution filtration process.

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P110013/S102	04/30/2020	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Addition of alternative equipment for manufacturing of foil pouches.
P110016/S068	04/16/2020	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Addition of an alternative bacterial endotoxin testing method.
P110027/S011	04/03/2020	X - 30-Day Notice	THERASCREEN KRAS RGQ PCR KIT	QIAGEN GMBH	Changes to in-process QC testing.
P110035/S058	04/13/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the sterilization cycle at the BSC Coventry, Rhode Island facility and the Steris Tullamore, Ireland contract sterilization facility.
P110035/S059	04/20/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to electropolishing process software.
P110041/S009	04/03/2020	X - 30-Day Notice	ADVIA CENTAUR HBSAGII	SIEMENS CORP.	Modification to the manufacturing process to add a second manufacturing site for optional sample handling subsystem (Atellica Direct Load) for the Atellica IM Analyzer (Immunoassay Module).
P110042/S136	04/07/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add an automated visual inspection system to the battery manufacturing process.
P120006/S034	04/24/2020	X - 30-Day Notice	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, INC.	Add a previously approved ethylene oxide sterilization supplier for the Alto Abdominal Stent Graft System.
P120011/S018	04/03/2020	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Add 100% visual inspection and manual flash removal from the valve seat after cryogenic deflashing.
P120021/S014	04/15/2020	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Reduce the inspection frequency of braided wire mandrels.
P120021/S015	04/16/2020	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Addition of an alternative bacterial endotoxin testing method.
P120022/S021	04/03/2020	X - 30-Day Notice	THERASCREEN EGFR RGQ PCR KIT	QIAGEN GMBH	Changes to in-process QC testing.
P130011/S009	04/03/2020	X - 30-Day Notice	FREEDOM SOLO STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Extend the maximum shipping time between abattoirs and the manufacturing site for bovine tissue from 48 hours to 96 hours.
P130013/S037	04/11/2020	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Adding an alternate heat treatment process for the final formed implant frame.

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P130017/S039	04/13/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing process changes at an approved supplier.
P130026/S056	04/06/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Changes to the optical fiber manufacturing process of the TactiCath Quartz contact force ablation catheter.
P130026/S059	04/16/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Addition of an alternative bacterial endotoxin testing method.
P130030/S068	04/02/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Automation of a component manufacturing process.
P140003/S071	04/09/2020	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Implementing a semi-automated test fixture for the leakage current measurement test performed during the final inspection for the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist, Impella LD, and Impella RP catheters.
P140028/S057	04/13/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update to the sterilization cycle at the BSC Coventry, Rhode Island facility and the Steris Tullamore, Ireland contract sterilization facility.
P140028/S058	04/22/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modified outer sheath PTFE stretching method.
P140028/S059	04/20/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to electropolishing process software.
P140031/S111	04/01/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Use of a new laser cutting plate material and modification of the associated laser cutting parameters.
P140031/S113	04/17/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Removal of two in-process dimensional inspections.
P140031/S114	04/29/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Alternative yarn supplier for the outer skirt component.
P140032/S050	04/02/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Clarify the USON Backflow test acceptance criteria for the test of the SynchroMed II implantable infusion pump to be more conservative.
P140032/S051	04/07/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Changes to the restock evaluation location and process for the SynchroMed II Infusion System. Restock processing for the product moved from the Rice Creek Facility to Medtronic's Distribution Centers and restock evaluation for the product has transitioned to evaluation using the Distribution Center Sorter Tool.
P140032/S052	04/22/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Reduction in frequency of Destructive Analysis (DA) sampling performed on battery headers undergoing laser welding at Medtronic Energy and Component Center.

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P150001/S083	04/16/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	New reclamation process to allow printed circuit board assemblies to be re-used for construction of refurbished 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.
P150003/S060	04/09/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the mechanism used to crimp the stent to its final profile.
P150011/S019	04/03/2020	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Extend the maximum shipping time between abattoirs and the manufacturing site for bovine tissue from 48 hours to 96 hours.
P150012/S093	04/16/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add a 100% visual inspection at a supplier to detect gaps in the inner coil component.
P150021/S048	04/13/2020	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Update to the in-process optical setup and image processing for the vision systems that verify three Critical Quality Attributes of the glucose sensor puck. The sensor is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Glucose Monitoring System.
P150031/S030	04/24/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an additional ethylene oxide (EO) sterilization chamber and associated sterilization process located at Boston Scientific Dorado Manufacturing site (BSC-DOR).
P150033/S068	04/06/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the Distribution Control Sorter Tool to make it compatible with other products.
P150033/S069	04/01/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Add identical tactile and visual inspections for exposed braid in the Micra delivery system.
P150033/S071	04/16/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the Post Sterilization Test used for manufacturing at the Medtronic Galway facility.
P150036/S051	04/14/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer the tube extrusion process for the balloon component from Irvine to Draper.
P150040/S005	04/02/2020	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Secondary supplier for the Patient Support System (PSS).
P160014/S016	04/27/2020	X - 30-Day Notice	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Minor change to the manufacturing of a packaging component.
P160017/S082	04/16/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	New reclamation process to allow printed circuit board assemblies to be re-used for construction of refurbished 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.
P160021/S026	04/08/2020	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Balloon tubing geometry change.

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P160024/S008	04/30/2020	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Modification to optimize the balloon manufacturing tooling.
P160030/S041	04/13/2020	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Update to the in-process optical setup and image processing for the vision systems that verify three Critical Quality Attributes of the glucose sensor puck. The sensor is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Glucose Monitoring System.
P160038/S016	04/28/2020	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	changes to the manufacturing processes
P160043/S035	04/30/2020	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Addition of alternative equipment for manufacturing of foil pouches.
P160054/S026	04/09/2020	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Qualify an alternate sub-supplier for the polyester raw material used in the manufacture of the HeartMate II Apical Sewing Ring and Percutaneous Cable as well as the HeartMate 3 Percutaneous Cable.
P160054/S028	04/16/2020	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Installation of additional data loggers for process monitoring at a manufacturing site.
P170008/S025	04/09/2020	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Expand the use of automation for the hydrophilic coating line of the delivery catheter.
P170011/S023	04/09/2020	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Implementing a semi-automated test fixture for the leakage current measurement test performed during the final inspection for the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist, Impella LD, and Impella RP catheters.
P170032/S006	04/28/2020	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTI ON, INC.	the introduction of an additional furnace for the heat set process of the WEB Aneurysm Embolization System implant
P170038/S003	04/16/2020	X - 30-Day Notice	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Installation of additional data loggers for process monitoring at a manufacturing site.
P180003/S002	04/10/2020	X - 30-Day Notice	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	In-process stent quality control changes, a component supplier manufacturing location change and part number changes.
P180011/S029	04/22/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modified outer sheath PTFE stretching method.
P180011/S030	04/20/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to electropolishing process software.
P180034/S002	04/15/2020	X - 30-Day Notice	TACK ENDOVASCULAR SYSTEM (6F)	INTACT VASCULAR, INC.	Transfer of tube cutting processes to a new site.

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P180043/S002	04/03/2020	X - 30-Day Notice	THERASCREEN FGFR RGQ RT-PCR KIT	QIAGEN GMBH	Changes to in-process QC testing.
P180046/S007	04/03/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Request to approve Hi-Tech Products, Inc. (HTP), as an alternate contract manufacturer to supply the Charge Adhesive Carrier,REF 9005.
P180046/S008	04/03/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Update to the sterilization load density at Parter Sterilization Services in Chambers 3 and 4.
P180046/S009	04/07/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Update to the Implantable pulse generator (IPG) Model 1101 for the following: 1) Ceramic case process change from machining to injection molding; and 2) Addition of alternate suppliers and manufacturability improvements for braze ring and titanium flange components.
P180046/S010	04/10/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Inclusion of NAMSA Inc. and LGGC Inc. as additional testing laboratories to perform biological indicator (BI) sterility testing and bacterial endotoxin testing (BET) for the Axonics Sacral Neuromodulation System.
P190001/S001	04/03/2020	X - 30-Day Notice	THERASCREEN PIK3CA RGQ PCR KIT	QIAGEN GMBH	Changes to in-process QC testing.
P190006/S007	04/03/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Request to approve Hi-Tech Products, Inc. (HTP), as an alternate contract manufacturer to supply the Charge Adhesive Carrier,REF 9005.
P190006/S008	04/03/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Update to the sterilization load density at Parter Sterilization Services in Chambers 3 and 4.
P190006/S009	04/07/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Update to the Implantable pulse generator (IPG) Model 1101 for the following: 1) Ceramic case process change from machining to injection molding; and 2) Addition of alternate suppliers and manufacturability improvements for braze ring and titanium flange components.
P190006/S010	04/10/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Inclusion of NAMSA Inc. and LGGC Inc. as additional testing laboratories to perform biological indicator (BI) sterility testing and bacterial endotoxin testing (BET) for the Axonics Sacral Neuromodulation System.
Total - 174					